NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL

May 18, 2007

National Institutes of Health Bethesda, Maryland

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on May 18, 2007 in Building 31, Conference Room 6, National Institutes of Health (NIH), Bethesda, MD. Dr. James F. Battey, Jr., Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed: May 18, 2007: 8:30 a.m. to 11:00 a.m. for review of individual grant applications; and

Open: May 18, 2007: 11:00 a.m. to 1:50 p.m, for the review and discussion of program development needs and policy.

Council members in attendance:1

Dr. Barry W. Ache

Dr. Margaretha Casselbrant

Dr. Jennifer Horner

Mr. Ronald Lanier

Dr. Sharon Moss

Dr. John J. Ngai

Dr. Donata Oertel

Ms. Myrna Orleck-Aiello

Dr. Lorraine Ramig

Dr. Steve Rauch

Dr. Brenda M. Ryals

Dr. Allen Ryan

Council members absent:

Ms. Donna Bates Boucher

Dr. Edward Conture

Dr. Nathan Fischel-Ghodsian

Dr. Susan Goldin-Meadow

Dr. Ernest Weymuller

1For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur. This procedure applies only to individual discussion of an application and not to "en bloc" actions.

Ex-Officio Members Not Participating:

Dr. Lucille B. Beck (represented at the Open Session by Dr. Kyle Dennis)

Dr. John R. Franks Dr. Michael E. Hoffer

The Council roster is found as Appendix 1.

Various members of the public, as well as NIDCD staff and other NIH staff, were in attendance during the open session of the Council meeting. A complete list of those present for all or part of the meeting is found in Appendix 2.

CLOSED SESSION

I. Call To Order and Opening RemarksDr. James F. Battey, Jr.

The meeting was called to order by Dr. Battey, Director, NIDCD, who welcomed members to Bethesda, and expressed appreciation to the entire Council for their service and advice. Dr. Edward Conture, Dr. Susan Goldin-Meadow, Dr. Nathan Fischel Ghodsian, Dr. Ernest Weymuller, and Ms. Donna Bates Boucher were unable to attend this meeting.

II. Council ProceduresDr. Craig A. Jordan

Procedural Matters

Dr. Jordan discussed important procedural matters, including requirements imposed by the Government in the Sunshine Act and the Federal Advisory Committee Act. The necessity of members to avoid conflict of interest, or the appearance thereof, was stressed, as was the need to maintain confidentiality concerning the proceedings and materials related to the closed portion of the meeting. Dr. Jordan announced that the Council meeting would be closed for consideration of grant applications during the morning session, but would be open to the public at approximately 11:00 a.m.

III. Council Consideration of Pending Applications

The Council gave special attention to applications involving issues related to protection of human subjects, animal welfare, biohazards and/or women/minority/children representation in study populations as identified by the initial review groups. The Council individually discussed applications being considered for High Program Priority, from New Investigators, and whenever additional discussion was required.

A. Research Project Grant Awards

1. <u>Consideration of Applications</u>: On the Council's agenda was a total of 99 investigator-initiated research grant applications; 79 applications had primary assignment to NIDCD, in the amount of \$23.88 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to award grants to R01 applications scoring up to the 21.9 percentile.

B. Special Programs Actions

- 1. Research Scientist Development Award (K08): The Council recommended support of one application.
- 2. <u>NIH Pathway to Independence (PI) Award (K99)</u>: The Council recommended support of two applications.
- 3. <u>NIDCD Research Core Center Grants (P30)</u>: The Council recommended support for four applications.
- 4. <u>Small Grants (R03)</u>: The Council recommended support for nine applications.
- 5. <u>NIH Support for Conferences and Scientific Meetings (R13)</u>: The Council recommended support for three applications.
- 6. <u>NIH Academic Research Enhancement Award (AREA) Grants (R15)</u>: The Council recommended support for two applications.
- 7. <u>NIH Exploratory/Development Research Grant Award (R21)</u>: The Council recommended support of five applications.
- 8. <u>Small Business Technology Transfer (STTR):</u> The Council recommended support for one Phase I (R41) application and two Phase II (R42) application
- 9. <u>Small Business Innovation Research Awards (SBIR):</u> The Council recommended support for two Phase I (R43) applications and five Phase II (R44) applications.
- 10. <u>RFA-DC07-004:</u> The Council recommended support for one application.
- 11. <u>RFA-DC07-005</u>: The Council recommended support for three applications.
- 12. <u>RFA-DC07-006</u>: The Council recommended support for one application.
- 13. <u>RFA-RR06-005</u>: The Council recommended support with NIDCD set-aside funds for this trans-NIH initiative.

OPEN SESSION

| Dr. | . Batte |
|-----|---------|
| | Dr. |

Dr. Battey welcomed additional staff and several visitors to the open session of the meeting

Consideration of Minutes of the Meeting of January 26, 2007

Dr. Battey called members' attention to the minutes of the January 26, 2007 meeting of the Advisory Council. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2008 have been established. A list of these meetings was distributed to the Council members and posted on the web site prior to this meeting. The next meeting of Council is scheduled for Friday, September 7, 2007, in Building 31, Conference Room 6 on the NIH campus, Bethesda, Maryland.

V. Report of the Director, NIDCD Dr. Battey

Budget Considerations:

Dr. Battey began his presentation with an update on changes to the budget since the January meeting. Efforts by Dr. Zerhouni and action by Congress led to a restoration of \$4.7 million dollars (previously set aside for RoadMap funding) to the NIDCD FY2007 budget. These additional funds have allowed the NIDCD to increase funding for R01 applications from earlier FY2007 Council meetings and for the current meeting.

Dr. Battey continued with a breakdown of the President's NIDCD Budget Request for FY 2007. He discussed how the \$277.2 million available for research project grants in the FY2007 President's Budget will be allocated. From this total, \$9.6 million is reserved for Small Business Research grants, \$1.25 million for administrative supplements, \$197.9 million for commitments to noncompeting grants, \$0.31 million for carryover commitments from prior Council meetings, \$8.3 million for program requirements, \$855 thousand for AIDS funding and \$2.7 million for NIH New Investigators funding. Twenty percent of the remaining \$56.3 million is designated for High Program Priority (HPP). Consequently, there is \$45.1 million available for the initial payline across the three Council meetings. This should allow funding of applications up to the 21.9 percentile. The \$11.3 million for HPP applications will be available to support additional applications. A copy of the slides Dr. Battey used for his budget presentation is included in these minutes as Appendix 3.

VI. Report of the Division of Scientific Programs, NIDCD...... Dr. Judith Cooper

In her report of the Director of the Division of Scientific Programs, NIDCD, Dr. Cooper discussed two new NIH funding programs being utilized by the NIDCD. These include NIH funding for new investigators and NIH bridge funding for competing continuations.

NIH Funding for New Investigators

Dr. Cooper explained that NIDCD defines a new investigator as one who is within ten years of a terminal degree and who has had no previous R01 support. This definition is different from that of NIH, with a new investigator defined as one who has had no previous R01 support. Congress allocated additional funds this year for NIH with the expectation of supporting an increased number of new investigators. NIDCD's goal is to fund 34 new investigators in FY07. So far this fiscal year, NIDCD has funded 23 new investigators and four more have been recommended for High Program Priority this Council round. A broader search for new investigators would include those within ten points of the R01 payline; using that criterion, seven additional applications from the January and May Council rounds would be included.

Dr. Cooper commented that this new funding is good news for NIDCD's principal investigators, as it will allocate additional funds to support our science areas, and more first-time R01 investigators will receive funding.

NIH Bridge Funding for Competing Continuations

Next, Dr. Cooper discussed another new funding program called the NIH Director's Bridge Award. This program was announced in March, and provides a single year of funding. It will be used only for R01 renewal applications. To qualify for this award, a Principal Investigator (PI) must be within ten points of the Institute's payline, have limited additional funding for his/her research, and first year requested costs. Based on this, five Pls have proven eligible for this award from the September 2006 and January 2007 Councils. Their applications were submitted to the Office of the Director, NIH and all five were approved for their full requested costs of the first year. They will receive an NIH Director's Bridge Award (R56) for one year of support. Dr. Cooper explained that this bridge funding does not jeopardize future funding, so that any continuation applications received from these R56 awardees will continue through the NIH peer review process. If an application does well in peer review and is within the payline, it will be held for funding until the end of the R56 award. The sequential two grants could potentially provide support for six years. She added that NIDCD has vetted and submitted three eligible applications from the May Council. A listing of NIH Director's Bridge Award recipients will be provided to Council at the September meeting. Dr. Cooper stated that this is additional good news for NIDCD Pls, in that previously unfunded NIDCD Pls will get one year of support and NIDCD will leverage NIH Director's funds to support our science areas.

In closing, Dr. Cooper commented that these two new programs have been a team effort,

and thanked the staff of the Division of Scientific Programs for identifying possible candidates; Mr. Chris Myers, Chief of the Grants Management Branch for helping to determine eligibility, and Dr. Craig Jordan, Director, Division of Extramural Programs, for helping to convey information to and from the Institute.

VII. Promotion of Hypothesis Generating Research...... Dr. Steven Rauch and Dr. Jordan

Dr. Steven Rauch led a discussion to brainstorm about how to deal with research proposals that are not designated as "hypothesis testing" projects. Dr. Rauch stated that there is a great deal of descriptive research and exploratory research that might be considered "hypothesis generating" but not "hypothesis testing." These projects are especially common in the clinical domain They tend to do poorly in study section, where reviewers are usually less sympathetic for the clinical point of view and the desperate need for these foundational studies. According to Dr. Rauch, this is a common topic of discussion among clinician-investigators around the country. After consulting with other NIH offices for how they have approached similar issues, Dr. Jordan suggested the need to reset the reviewers' "mindset" by one or more of the following:

- Using a targeted solicitation (RFA/PAR) that specifically targets design-directed, developmental, discovery-driven, or hypothesis-driven research;
- use mechanism other than R01 to avoid the R01 mindset;
- have a dedicated review panel;
- have a special orientation for reviewers, <u>before</u> they start their review assignments and include a good explanation of why the IC considers this to be an important component of its research.

During the Council discussion there was general support of the concept and members pointed out examples from their own areas of science. In order to generate new ideas and/or approaches, one first needs to develop the environment, or the foundational data, to nurture such endeavors. The peer review of such discovery driven research efforts are critical and care needs to be exercised in developing the review criteria and the expectations for a theoretical grounding. Such efforts should help ensure that discovery driven efforts would directly lead to hypothesis testing research.

VIII. Scientific Presentation Dr. Doris Wu

Next, Dr. Battey introduced Dr. Doris Wu, Division of Intramural Research, NIDCD., where she serves as Acting Chief, Section on Sensory Cell Regeneration and Development, Laboratory of Molecular Biology. Dr. Wu accepted the invitation to discuss her research in identifying genes that are important in the development of the inner ear.

An abstract of Dr. Wu's presentation follows:

"The Making of an Inner Ear"

The mammalian inner ear is an intricate organ that develops from a simple epithelium. Tissues surrounding the developing inner ear such as the neural tube, mesoderm, endoderm, and neural crest are thought to provide inductive signals required for its formation. We showed that two ventral midline structures, the notochord and floor plate, provides a graded level of Sonic hedgehog (Shh) to pattern the inner ear along the dorsal-ventral axis. The otic epithelial region positioned closest to the ventral midline, requires relative high levels of Shh to activate transcription factors, Gli2 and Gli3, in order to form the apical cochlear duct. In contrast, the dorsal vestibular region that is located farthest away from the ventral midline, requires the least amount of Shh. Under low levels of Shh, the Gli3 transcription factor is truncated and the N-terminal form of the protein functions as a transcription repressor. This transcription repressor activity of Gli3 is essential for the formation of dorsal vestibular structures.

Low frequency hearing loss is associated with Pallister-Hall syndrome. In these patients, mutations in GLI3 resulted in an N-terminal truncated form of GLI3 protein that is thought to retain only its repressor activity and not its activator functions. Inner ear analyses of a mouse mutant, $\delta 699/\delta 699$, in which the mutation in the Gli3 gene is modeled after mutations reported in Pallister-Hall patients, showed that the cochlear duct of these mutants is shortened. Gene expression results suggest that the cochlear duct is shortened because it is missing the apical region of the duct. We attributed this phenotype partially to the lack of Gli3 activators. In addition, the mutant form of Gli3 repressor blocks other Gli activators required for apical cochlear duct development in a dominant negative fashion. Since the apical region of the cochlear duct detects low frequency sounds in both humans and mice, the failure of apical cochlear duct formation in $\delta 699/\delta 699$ mutants is consistent with the low frequency hearing loss observed in patients with Pallister-Hall syndrome.

IX. Reports on CSR Open House Meetings...... Dr. Barry Ache and Dr. Lori Ramig

The NIH's Center for Scientific Review (CSR) is hosting six one-day Open House Workshops in 2007 to solicit input from leaders of the scientific community and other stakeholders on the alignment of its Integrated Review Groups (IRGs) and component study sections, which assess NIH grant applications for scientific and technical merit. The IRGs have not been broadly assessed by the scientific community since the NIH Panel on Scientific Boundaries for Review (PSBR) developed a reorganization plan seven years ago. Convening the Open Houses represents a comprehensive effort to engage stakeholders from all the many scientific disciplines to ensure their voices are heard and CSR's review groups are properly aligned and prepared for the future.

Dr. Barry Ache represented the NDCD Advisory Council at the Open House for the Neuroscience IRGs which was held on March 2 and Dr. Lori Ramig represented the Council at the Open House for Behavioral and Social Science IRGs on April 24. They

reported on the outcomes of each of those workshops. Copies of each of their summary reports had been previously provided to Council and are included in these minutes as Appendix 4.

Additional information about the CSR Open Houses can be found on the web at: http://cms.csr.nih.gov/AboutCSR/ReportStorage/openhousereports.htm

X. Adjournment: The meeting was adjourned at 1:50 p.m. on May 18, 2007.

XI. Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct.²

7-9-07

Craig A. Jordan, Ph.D.

Executive Secretary

National Deafness and Other Communication

Disorders Advisory Council

7-14-07

James F. Battey, Jr., M.D., Ph.D.

Chairman

National Deafness and Other Communication

Disorders Advisory Council

Director

National Institute on Deafness and Other Communication Disorders

Jeannie Combs Council Assistant

² These minutes will be formally considered by the NDCD Advisory Council at its next meeting; corrections or notations will be incorporated in the minutes of that meeting.

APPENDICES

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Appendix 1

Roster

National Deafness and Other Communication Disorders Advisory Council

Chairperson

James F Battey, Jr., M.D., Ph.D., Director National Institute on Deafness and Other Communication Disorders Bethesda, Maryland 20892

2009

ACHE, Barry W., Ph.D 2007
Director, Center for Smell and Taste
Distinguished Professor of Zoology
and Neuroscience, Whitney Laboratory
University of Florida
Gainesville FL

BATES-BOUCHER, Donna Bates Group, Inc. Eight Hyde Park Circle Denver, CO

CASSELBRANT, Margaretha, Ph.D. 2010 Director Department of Pediatric Otolaryngology Children's Hospital of Pittsburgh University of Pittsburgh School of Medicine Pittsburgh, PA

CONTURE, Edward G., Ph.D. 2008
Professor and Director, Graduate Studies
Vanderbilt University Medical Center
DHSS Graduate Studies and Research
Vanderbilt University
Nashville, TN

FISCHEL-GHODSIAN, Nathan, M.D. 2009 Professor of Pediatrics Cedars-Sinai Medical Center Los Angeles, CA

GOLDIN-MEADOW, Susan J., Ph.D. 2008
Beardsley Ruml Distinguished
Service Professor
Department of Psychology
Division of Social Sciences
University of Chicago
Chicago, IL

HORNER, Jennifer, J.D., Ph.D.

Associate Professor and Chair Department of Rehabilitation Sciences Medical University of South Carolina Charleston, SC

2008

LANIER, Ronald L.
Director
Virginia Department for the Deaf
and Hard of Hearing
Commonwealth of Virginia
Richmond, VA

MOSS, Sharon E., Ph.D. 2008
Director
Scientific Programs and Research
Development
Speech-Language-Hearing Science
and Research Institute
American Speech-Language-Hearing Assoc.
Rockville, MD

NGAI, John J., Ph.D. 2007 Professor of Neurobiology Department of Molecular and Cell Biology University of California Berkeley, CA

OERTEL, Donata, Ph.D. 2007
Professor
Department of Physiology
University of Wisconsin
Madison, WI

2010

ORLECK-AIELLO, Myrna "MO" 2009
CEO/President
Abacus N Bytes, Inc.
D/B/A TCS Associates
Technical Computer Services
Wheaton, MD

RAMIG, Lorraine, Ph.D., CCC-SLP 2010 Professor Department of Speech Language Hearing Sciences University of Colorado, Boulder Boulder, CO

RAUCH, Steven D., M.D. 2010 Associate Professor, Otolaryngology Department of Otology & Laryngology Harvard Medical School Massachusetts Eye and Ear Infirmary Boston, MA

RYALS, Brenda M., Ph.D. 2007
Professor
Dept of Communication Sciences &
Disorders
James Madison University
Harrisonburg, VA

RYAN, Allen F., Ph.D. 2009
Professor of Surgery/Otolaryngology
Department of Surgery
University of California at San Diego
La Jolla, CA

WEYMULLER, Ernest A., M.D. 2009
Chair and Professor
Department of Otolaryngology-HNS
University of Washington
School of Medicine
Seattle, WA

EX-OFFICIO MEMBERS:

BECK, Lucille B., Ph.D. Director Audiology & Speech Pathology Service Department of Veterans Affairs Wash

FRANKS, John R., Ph.D.
Chief, Bioacoustics and
Occupational Vibration Section
Physical Agent Effects Branch
Division of Biomedical and Behavioral Science
National Inst for Occupational Safety & Health
Cincinnati, OH

HOFFER, Michael E., M.D.
Co-Director
Department of Defense Spatial Orientation
Center
Department of Otolaryngology
Naval Medical Center
San Diego, CA

LEAVITT, Michael
Secretary
Department of Health and
Human Services
Hubert H. Humphrey Building
Washington, DC

ZERHOUNI, Elias A., M.D. Director National Institutes of Health Bethesda, MD

EXECUTIVE SECRETARY

JORDAN, Craig A., Ph.D.
Director
Division of Extramural Activities
National Institute on Deafness
and Other Communication Disorders
Bethesda, MD 20892-7180

Appendix 2

ATTENDANCE LIST

Other than Council members, attendees at the May 18, 2007 Council meeting included:

NIDCD Staff:

Office of Administration

Kerr, W. David, Executive Officer

Financial Management Branch

Rotariu, Mark, Chief Langston, Catherine, Budget Analyst

Science Policy and Planning Branch

Wong, Baldwin, Chief
Cole, Laura, Science Policy Analyst
Montney, Lisa, Science Policy Analyst
Stewart, Lesley, Presidential Management Intern

Division of Extramural Activities

Jordan, Craig A., Ph.D., Director Stephenson, Nanette, Program Assistant

Grants Management Branch

Myers, Christopher, Chief
Dabney, Sherry, Grants Management Officer
Doan, Hoai, Grants Management Specialist
Garcia, Maria, Grants Management Specialist
McNamara, Castilla, Ph.D., M.P.A., Grants Management Specialist
Myrbeck, Eddie, Grants Management Specialist
Ranney, Meigs, Grants Management Officer

Scientific Review Branch

Stick, Melissa, Ph.D., M.P.H., Chief Livingston, Christine, Ph.D., Scientific Review Administrator Oaks, Stanley C., Ph.D., Scientific Review Administrator Singh, Sheo, Ph.D., Scientific Review Administrator Yang, Shiguang A., Ph.D., Scientific Review Administrator

Division of Scientific Programs

Cooper, Judith, Ph.D., Director

Voice, Speech, Language, Smell and Taste Branch

Cooper, Judith, Ph.D., Program Director, Language Program
Davis, Barry, Ph.D., Program Director, Smell and Taste Program
Shekim, Lana, Ph.D., Program, Director, Voice & Speech Program
Sklare, Daniel A., Ph.D., Program Director, Research Training and
Development Program

Hearing and Balance/Vestibular Branch

Donahue, Amy, Ph.D., Chief Freeman, Nancy, Ph.D., Program Director, Hearing Miller, Roger, Ph.D., Program Director, Hearing Platt, Christopher, Ph.D., Program Director, Balance/Vestibular Watson, Bracie, Ph.D., Program Director, Hearing

Translational Research Branch

Chin, Ling, M.D., MPH, Chief Hoffman, Howard, Program Director for Epidemiology & Biostatistics

Division of Intramural Research

Wu, Doris, Ph.D., Acting Chief, Section on Sensory Cell Regeneration and Development, Laboratory of Molecular Biology

Division of Extramural Administrative Support, OER, NIH

Holmes, Debbie, Extramural Support Assistant Johnson, Barbara, Grants Clerk Horton, Nabriya, Grants Clerk

Center for Scientific Review, NIH

Clayton, Edwin, Ph.D., Scientific Review Administrator
King, Jonathan W., Ph.D., Scientific Review Administrator (Intern)
Kenshalo, Daniel, Scientific Review Administrator
Martin, Michael, Ph.D., Scientific Review Administrator
Melchior, Christine, Ph.D., Chief, Integrative, Functional, and Cognitive Neuroscience IRG
Ni, Weijia, Ph.D., Scientific Review Administrator
Plude, Dana, Ph.D., Chief, BBBP
Tian, Biao, Ph.D., Scientific Review Administrator

Others

Dennis, Kyle, Ph.D., Veteran's Administration
Thomas, Kate, American Academy of Audiology
Kobor, Patricia, Senior Science Policy Analyst, American Psychology Association
Outlaw, Deborah, Attorney, American Tinnitus Association

Appendix 3

NIDCD Director's Report Slides

As Presented By

James F. Battey, Jr., M.D., Ph.D. Director, NIDCD

NDCD Advisory Council Meeting

May 18, 2007

National Institute on Deafness and Other Communication Disorders

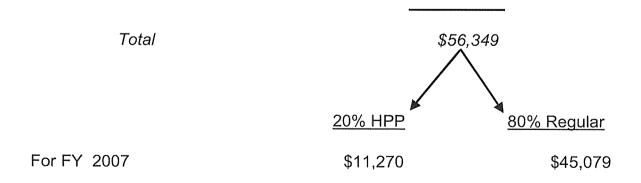
May 2007 Council Budget Mechanism (Dollars in thousands)

| | | | | President's |
|--------------------------|---------|---------------|---------|-------------|
| | FY 2007 | Appropriation | FY 2008 | Request |
| Budget Mechanism | Number | Amount | Number | Amount |
| Research Projects | | | | |
| Noncompeting | 633 | \$199,249 | 625 | \$198,134 |
| Admin. Supplements | (26) | 1,250 | (23) | 1,050 |
| Competing | 231 | 67,130 | 225 | 65,275 |
| Subtotal | 864 | 267,629 | 850 | 264,459 |
| SBIR/STTR | 30 | 9,600 | 28 | 9,000 |
| Subtotal, RPG's | 894 | 277,229 | 878 | 273,459 |
| Research Centers | 20 | 17,252 | 20 | 17,079 |
| Other Research | 63 | 10,156 | 65 | 9,962 |
| Total Research Grants | 977 | 304,637 | 963 | 300,500 |
| Individual Training | 154 | 5,900 | 141 | 5,418 |
| Institutional Training | 187 | 7,700 | 180 | 7,417 |
| R & D Contracts | 52 | 22,420 | 50 | 21,961 |
| Intramural Research | | 34,905 | | 35,032 |
| Research Mgmt. & Support | | 18,106 | | 18,179 |
| NIH Roadmap | | 0 | - | 5,175 |
| TOTAL | | \$393,668 | | \$393,682 |

National Institute on Deafness and Other Communication Disorders

May 2007Council Competing Research Project Grants (Dollars in thousands)

| Total RPG Funds FY07 Appropriation | \$277,229 |
|---|-----------|
| Less SBIR/STTR Budget | -9,600 |
| Less Administrative Supplement Budget | -1,250 |
| Less Noncompeting updated estimate | -197,952 |
| Less FY07 "Carryover" Commitments from prior Council meetings | -307 |
| Less FY07 Program Requirements | -8,250 |
| Less FY07 AIDS co-funding | -855 |
| Less FY07 NIH New Investigators funding | -2,666 |



Appendix 4

Report to Council on the NIH Center for Scientific Review (CSR) Neuroscience Open House Workshop on March 2, 2007

Prepared by Dr. Barry Ache

Approximately 200 participants met at the Natcher Auditorium, which represented about equal numbers of outside 'stakeholders' and NIH staff. Following introductory remarks by Drs. Elias Zerhouni, Director of NIH, and Dr. Tony Scarpa, Director of CSR. CSR senior staff outlined the evolution of the current structure of the neuroscience initial review groups (IRGs) and their component study sections within CSR.

Staff presentations explained how the current complement of study sections came about as a result of the 1998 reorganization and how IRGs are continuously being evaluated and realigned to better serve stakeholders and the changing demands of science. The main goal of the reorganization and subsequent changes since has been to reduce study section 'captivity', i.e., not to have study sections whose grants go to only one institute, and allow any one proposal to have several sources of review while having at least one clear 'home'. The process of aligning study sections is relatively dynamic. One IRG showcased was restructured twice in two years. This process has led to 29 study sections under three IRGs currently dedicated to neuroscience.

A question and answer session was largely confounded by stakeholders wanting to discuss 'process' and the organizers wanting to limit the conversation to the goal of the workshop, which was to identify problems with current study section alignments and emerging needs for future alignments. A recurring issue raised by stakeholders here and at the end of the workshop was to consider addressing the score compression that inevitably accompanies tight funding by having study sections rank order top proposals and not solely rely on the current numerical (percentile) scoring.

The main element of the meeting was six parallel breakout sessions focusing on: (1) cellular and molecular neuroscience, (2) developmental neuroscience, (3) behavioral and sensory neuroscience, (4) disorders of the nervous system, (5) neuroendocrinology, neuroimmunology, and neurogenetics, and (6) neurotechnology, neuroimaging, and neuroinformatics. A number of recommendations appeared across multiple sessions:

- 1) Issues with current study section alignments:
 - Expand expertise and overlap of study section composition to better cover complex, multidisciplinary (including translational) research;
 - Populate study sections to better evaluate the use of all animal models, including non-genetic ones;

- Increase study section breadth by making more use of senior scientists and identify ways to get them to serve;
- Seek more input from professional societies in determining study section composition.
- 2) Emerging questions/technologies in the next 10 years:
 - Computational neuroscience and modeling;
 - Bioinformatics and large-scale data handling and sharing;
 - Increasing role for integrative/systems physiology and behavioral research;
 - Genes and environmental interactions in development and disease.

Dr. Scarpa ended the workshop by briefly describing the following changes currently being considered to the peer review process to address concerns that the process is too slow, doesn't effectively utilize senior scientists, favors predictable research, and puts undue burden on reviewers:

Recruit and retain higher quality reviewers by:

- Abolishing submission deadlines for them and fund their grants for a longer period of time:
- Reduce travel by moving towards electronic reviews—but not to replace face-to-face meetings;
- Reduce meeting length;
- Reduce length of applications—favored by scientists 3/1, n=5,078;
- Better evaluate translational research by thinking outside the box, not just adding more reviewers:
- Continue to foster new investigators—currently their success rate is similar to that of established investigators submitting a new proposal;
- Saving on travel by going away from open to restricted ticketing;
- Continuing to improve study section alignment based on the recommendation of this and subsequent workshops;
- Shortening the review cycle to allow three submissions per year by increasing efficiency, e.g., electronic submission, electronic assignment currently posting results within one month.

Some interesting numbers

| | 5 yrs ago | now |
|-----------------------------|-----------|--------|
| # applications received/yr | 46,000 | 80,000 |
| # R21, R01s reviewed by CSR | 21,000 | 39,000 |
| # applications/applicant | 1.2 | 1.4 |
| # applications/reviewer | 11.6 | 6.0 |

Report to Council on the NIH Center for Scientific Review (CSR) Behavioral and Social Sciences Open House Workshop on April 25, 2007

Prepared by Dr. Lori Ramig

Dr. Raynard Kington, Deputy Director of NIH and Dr. Tony Scarpa, Director of CSR welcomed the group of approximately 150 attendees, composed of NIH staff and outside 'stakeholders'. Dr. Anita Miller Sostek, Director of the Division of Clinical and Population-Based Studies provided an overview of the current organization of the behavioral and social sciences study sections.

Dr. Sostek's presentation provided the history of the study section organization and reorganization. A major goal of reorganization is to have a number of sources of review to accommodate evolving science. She was very clear that this continues to be a dynamic process.

Dr Cheryl Kitt, Deputy Director of CSR, then provided the charge to the breakout groups.

There were six parallel breakout groups:

- Basic Behavioral Science 1
- Basic Behavioral Science 2
- Epidemiology and Biostatistics
- Health Services and Demography
- Risk, Intervention, Prevention: Individual or Small Group Level (RIP-S)
- Risk, Intervention, Prevention: Large Group or Community Level (RIP-L)

We spent the bulk of the day in breakout groups addressing these questions:

- 1) Is the science of your discipline, in its present state, appropriately evaluated within the current study section alignment? Suggestions?
- 2) What will the most important questions and/or enabling technologies you see forthcoming within the science of your discipline in the next 10 years?

Stake holders engaged in spirited discussions in each of two sessions addressing these issues. The complete report from this meeting will be posted on the NIH website: http://www.csr.nih.gov/openhousereports/

In summary, stake holders did a good job of representing their constituents and their own line of study in their remarks. The global conclusion was that the science of our discipline was being appropriately evaluated within the current study section alignment. There was a

clear expression to maintain foundational research approaches and continue a combination of breadth (big picture understanding of the discipline) and depth (expert on specifics) in the review process. There was an expression of need for continued interdisciplinary review. Among the underrepresented areas noted included neuropsychology and treatment science. The discussion of the future included dissemination science, economic and environmental elements in design, practical and ethical issues around large scale data sharing, translational research, technology enhanced data acquisition and delivery of interventions to name a few examples.

The workshop concluded with Dr. Scarpa discussing the changes suggested to the review process. A guiding principle is that the "review process is as good as the reviewers". Dr Scarpa described some of the changes in the process including electronic review, shortening the review cycle, shorter applications.

He mentioned ways to improve reviewer recruitment by adding value to study section membership in the academic setting, eliminate submission deadlines and fund reviewers' grants for a longer time period. He showed a slide of the first study section in 1946 and one today (see attached). See the report for OpenHouse #1 for comparative data from 5 years ago and today on grants submitted and reviewed.